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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,494	01/21/2004	Paul Ashton	CDSI-P01-005	4368

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EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary

Application No.

10/761,494

Applicant(s)

ASHTON ET AL

Examiner

Charanjit S. Aulakh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1 page.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 20 July 2005.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-53 are pending in the application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-52, drawn to Pharmaceutically acceptable salt of a codrug wherein the codrug is represented by compounds of formulae IV, V, VI and VII (see claims 15-20) and a method of treating pain using this codrug, classified in class 546, subclasses 44, 45, 46 and 74.

II. Claims 1-14, 23, 25-37 and 39-53, drawn to Pharmaceutically acceptable salt of a codrug of different structural formulae other than defined above for group I and a method of using this codrug, classified in classes 540, 544, 546, 548, 549 etc, numerous subclasses within each class.

3. The inventions I and II as defined above are patentability distinct, each from the other since they are structurally so divergent that a reference showing compounds of invention I would not render compounds of invention II prima facie obvious. Search required for e.g ; compounds of invention I in class 546 is not the same search required for e.g ; compounds of invention II in classes 540, 544, 548 etc. and therefore, constitutes a burdensome search.

4. During a telephone conversation with the applicant's attorney, Mr. David P. Halstead on July 20, 2005, a provisional election was made with traverse to prosecute the invention of group I, claims 1-52. Affirmation of this election must be made by applicant in replying to this Office action. Claim 53 is withdrawn from further consideration by the

examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It is of note that group II is subject to further restriction based on the structural formulae of codrugs in the future applications.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 50, it is not clear whether it is an acid which treats at least symptom or is it codrug which treats at least one symptom. Also, the term ---at least one symptom of a condition--- is indefinite since the specific symptoms or conditions are not defined.

In claim 51, the term ---relieving--- is indefinite since the degree of relief (20%, 40%, 60%, 80% or 100%) is not defined and furthermore, it is not clear how this relief is being assessed following administration of this codrug?

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-52 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Ashton (WO 02/098427, cited on applicants form 1449).

Ashton discloses Sustained-release analgesic compounds. The salt of codrug (see compound 10 in scheme 5 on page 35 and example 15 on page 29) for treating pain. (see claim 43) disclosed by Ashton clearly anticipate the instant claims.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Riess (U.S. Patent 5,190,947).

Riess discloses codeine salt of a substituted carboxylic acid, pharmaceutical compositions containing it and a method of treating pain using this codeine salt. The salts disclosed in examples 1-3 (see col. 6 and 7 as well as claims 1-3) disclosed by Riess clearly anticipate the instant claims.

10. Claims 1-52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Asmussen (U.S. Patent 6,156,764).

Asmussen discloses Morphine and diamorphine salts of anionic non-narcotic analgesics for treating pain. The morphine and diamorphine salts of diclofenac (see formula 1 in col. 2, lines 7-42 as well as claims) disclosed by Asmussen clearly anticipate the instant claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made..

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (EP 0 649 657, cited on applicants form 1449) in view of Guo (Proceed. Intern. Symp. Control. Rel. Bioact. Mat., cited on applicants form 1449).

Miller discloses pharmaceutical combinations containing a NSAID and an opioid analgesic for treating arthritic pain. The combination of codeine phosphate and diclofenac sodium (see example 2 on page 6 as well as claim 6) disclosed by Miller meets all the limitations except that it does not teach or mention preparing codrug. However, Guo teaches a novel delivery strategy for sustained release of synergistic agents by conjugating two synergistic agents together to form a low solubility codrug. Therefore, one skilled in the art would have been motivated to prepare codrug of

codeine phosphate and diclofenac sodium since Guo teaches advantages of codrug delivery system (see conclusion in Guo's article).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6, 8, 20-22 and 28 of copending Application No. 10/316,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because salts of codrugs of claims of the cited application encompasses the salt of codrug of instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-14, 23, 25-37 and 39-52 are objected for containing non-elected subject matter.

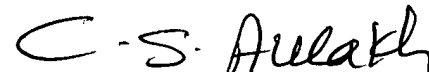
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is

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(571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
Art Unit 1625